Canon

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DATE: June 1, 1999
REF: QMP-1074-99

Mr. Jerome Dennis
Food and Drug Administration
Center for Devices and Radiological Health
Dockets Management Branch (HFA-305)
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Subject: Comments Regarding The Proposed Amendment To The Laser Products Performance Standard, Docket No. 93N-0044

Dear Mr. Dennis:

Please accept this letter as Canon's formal comments in response to the Federal Register notice published on March 24, 1999 (Vol. 64, No. 56) regarding the proposed amendment of the laser performance standard.

Our comments are as follows:

1. Effective Date

   For laser products which are in compliance with the current laser performance standard, we would like to request that the FDA establish a transitional period of at least three years before applying the new performance standard to the current model laser products. Many aspects of each existing product would need to be reevaluated such as modification of classification labels affixed on the products when the new performance standards becomes effective.

2. Product Reporting Alternative For Reclassifying Class IIa Products

   Some laser products would be required to be reclassified to comply with the proposed amendment. Due to this fact, we would like to propose an alternate method for identifying products that would need to be reclassified from Class IIa to Class 2 (i.e., an abbreviated application or update to the annual report).

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3. Minor Modification To Table 7

   We believe that the wording "or LED radiation" which appears at the end of the sentence in the first paragraph of Table 7 should be deleted since LEDs are not in the scope of this performance standard.

4. Typographical Error In 1040.10(d)(5)

   We think that the numbering (d)(4) appears in 1040.10(d)(5) and that it should be numbered as (d)(5) throughout this subsection.

5. Clarification Regarding 1040.10 (h)(1)(vi)

   Although section 1040.10(e)(3)(i)(D) is the measurement method for determining whether there is a need to provide a warning to users, it is basically intended to be applied to the "wavelength range less than 400 nm and greater than 1,400 nm" at the time of classification. Therefore, it is obvious that Class 1 products operating within these wavelength ranges would not have 1040.10(e)(3)(i)(D) measurement result exceeding Class 1 limit. So, we believe there is a conflict with the application of 1040.10(h)(1)(vi) for Class 1 products with wavelength range less than 400 nm and greater than 1400 nm.

If you have any questions regarding the above comments, please feel free to contact me at 516-328-5602 or by fax at 516-328-5169. Thank you.

Sincerely,

Ken Shadoff
Senior Product Safety Engineer
Quality Management Dept.

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